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April 19, 2022

Via CM/ECF & e-Mail
Hon. Analisa Torres
United States Courthouse
500 Pearl Street
New York, NY 10007

Re: ***Sugar v. Prevail Therapeutics Inc.***, No. 22-CV-1260

Dear Judge Torres:

I write to advise that Defendant Prevail Therapeutics Inc. ("Prevail") intends to move to dismiss Plaintiffs' Complaint.

Pursuant to Rule III.B of Your Honor's Individual Practices in Civil Cases, Prevail advised Plaintiffs' counsel by letter dated April 4, 2022 of its intent to move to dismiss Plaintiffs' claims. Plaintiffs' counsel did not respond by the Court's deadline, and when prompted, Plaintiffs' counsel responded with a one-sentence e-mail that stated: "I do not accept any of your arguments." Now, pursuant to Rule III.A, Prevail advises the Court of its intent to file a motion to dismiss Plaintiffs' Complaint for the reasons set forth below.

Factual and Procedural Background

Plaintiff Ross Sugar, M.D., is afflicted with Parkinson's disease and Gaucher's disease, which forced his retirement as a physician. In early 2020, Dr. Sugar sought out and ultimately enrolled in an experimental, first-in-human study of a novel gene therapy (PR001) developed by Prevail for treatment of Parkinson's. Prevail sponsored the study, and Dr. Sugar traveled from his home in Maryland to receive the treatment at Weill Cornell Medical College. *See* Complaint, ¶¶ 1, 8-13.

Before Dr. Sugar received his one-time treatment with PR001, he reviewed and signed an extensive informed consent form that advised him of the potential risks of the study, including the experimental, first-in-human nature of the clinical trial, the possibility of risks that are "not known," and the potential for "very serious and/or fatal" adverse events, including "inflammation of the area surrounding the brain and spinal cord." Dr. Sugar's wife, Plaintiff Julie Sugar, also received and signed an informed consent form. *See* Complaint, ¶¶ 20-21; Complaint, Ex. A, at 13-18; Complaint, Ex. B.

A few months after he received his one-time treatment with PR001, Dr. Sugar experienced adverse health events — specifically, alleged immune or inflammatory reactions — that required hospitalization and rehabilitation. Plaintiffs allege that these adverse health events are attributable to Dr. Sugar's PR001 treatment. Plaintiffs also contend that Dr. Sugar continues to experience

adverse health effects attributable to PR001, and they further allege that Prevail has breached an agreement with the Sugars because it has not reimbursed them for unspecified costs they attribute to Dr. Sugar's PR001 treatment.

Plaintiffs' Tort Claims

As an initial matter, Plaintiffs' tort claims[1] fail because New York appellate precedent establishes that clinical trial sponsors do not owe tort duties to clinical trial study subjects. In *Wholey v. Amgen, Inc.*, a clinical trial subject sued a drug manufacturer, alleging that she suffered injuries from an experimental treatment. 86 N.Y.S.3d 16 (N.Y. App. Div. 2018). The Appellate Division, First Department held that the plaintiff could not pursue those claims because, "[a]s the sponsors of a clinical trial, defendants owed no duty to plaintiff Lauren Wholey, an enrollee in the trial." *Id.* at 17. This precedent forecloses Plaintiffs' tort claims here.

Setting aside the absence of a tort duty, Plaintiffs' tort claims still fail as a matter of law for numerous independent reasons.

First, any theory based on an alleged failure to warn — which is where Plaintiffs appear to focus their allegations — fails as a matter of law because the allegations in the Complaint show that study investigators and Plaintiffs themselves received robust warnings of the potential risks of treatment with PR001, including the experimental, first-in-human nature of the trial and the related potential for risks that are "not known"; the potential for "very serious and/or fatal" adverse events; and the risk of immune reactions and inflammatory responses, including "inflammation of the area surrounding the brain and spinal cord." Complaint, Ex. A, at 13, 14, 15.

Because these warnings "provide[d] specific detailed information on the risks of the drug," they were adequate as a matter of law, *Martin v. Hacker*, 83 N.Y.2d 1, 10 (N.Y. 1993),[2] especially given that the study investigators — and Dr. Sugar — were physicians who understood the medical issues and risks conveyed to them.

Plaintiffs' principal criticisms appear to be that (1) the informed consent did not include the medical term "encephalitis" and (2) an updated informed consent form provided to Plaintiffs ***after*** Dr. Sugar's alleged adverse events did not, in Plaintiffs' view, accurately describe his injuries. As to the first of these, the informed consent expressly captured the alleged injuries at hand, including by warning of "very serious and/or fatal" adverse events and the risk of immune reactions and inflammatory responses, including "inflammation of the area surrounding the brain and spinal cord." Plaintiffs have not alleged specific facts to suggest that adding the medical term encephalitis (inflammation of the brain) would have materially changed the nature of the risk or that Prevail had any specific knowledge of the need to do so. As for the updated informed consent, even if the alleged inaccuracies were true — which Prevail denies — they would be entirely irrelevant. As the Complaint acknowledges, Plaintiffs received the updated consent ***after*** Dr. Sugar's experimental treatment with PR001 had ended, and ***after*** his hospitalization. Complaint,

[1] Plaintiffs assert tort claims in their second through eighth causes of action. One of the claims (the second cause of action) alleges strict liability, while the others rest on negligence theories.

[2] *See also Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 97-98 (N.Y. App. Div. 1979).

¶ 63 & Ex. C (updated informed consent dated July 15, 2020). The updated consent therefore could not have had any causal relationship to the alleged injuries.

Second, Dr. Sugar's warning claims fail under the learned intermediary doctrine. Although New York appears not to have addressed the issue specifically (since no tort duties apply in this setting), other jurisdictions have made clear that the learned intermediary doctrine applies in clinical trials of medicines and medical devices — just as it applies to approved pharmaceuticals or devices. *See, e.g.*, *Butler v. Juno Therapeutics, Inc.*, 541 F. Supp. 3d 774, 785-88 (S.D. Tex. 2021). Here, Plaintiff has not alleged facts that could establish that Prevail failed to warn the investigator-physicians who oversaw his treatment, or that a different warning would have caused the investigators to exclude Dr. Sugar from the clinical trial. *See Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 285 (S.D.N.Y. 2009). Indeed, the Complaint does not describe any effect of alleged warning inadequacies on investigator decision-making at all. For these reasons, the warnings-based claims would fail even if Plaintiffs could establish some deficiency in the warnings.

Third, Plaintiffs' tort claims fail to the extent that they rely on alleged violations of provisions in the Code of Federal Regulations governing clinical trials. *See* Complaint, ¶¶ 113-15, 139-41 (citing 21 C.F.R. §§ 312.50, 312.60; 45 C.F.R. § 46.116(a)). There is no federal cause of action for alleged personal injuries arising in the setting of a clinical trial. Moreover, Prevail is unaware of any New York court having adopted the cited regulatory provisions to establish state-law duties, under a negligence *per se* theory or otherwise; indeed, as noted, New York does not recognize sponsor tort duties at all. Furthermore, Plaintiffs have not alleged facts showing any violation of the cited provisions, which — on their face — do not establish any duty to obtain informed consent on the part of sponsors. *See id.* For these reasons, Plaintiffs' fifth and seventh causes of action would independently fail as a matter of law.

Fourth, to the extent that Plaintiffs intend to proceed on a design defect theory, Plaintiffs' Complaint is devoid of factual allegations that, if true, would establish that PR001 was defective in its design or that a feasible alternative design was available. *See Gonzalez v. Delta Int'l Mach. Corp.*, 763 N.Y.S.2d 844, 846 (N.Y. App. Div. 2003). Similarly, Plaintiffs do not allege facts supporting a manufacturing defect theory — *i.e.*, that the PR001 administered to Dr. Sugar deviated from its design and that such deviation caused injury. *See Miccio v. ConAgra Foods, Inc.*, 224 F. Supp. 3d 200, 204 (W.D.N.Y. 2016). Plaintiffs therefore have not pleaded any cause of action based on a theory of defective design or manufacturing.

Fifth, certain tort counts fail for the additional reason that New York law simply does not recognize them. Prevail is unaware of any recognized claim for "negligent human subject research," nor of any stand-alone claim for "breach of fiduciary duty" in this setting (other than a negligence claim, which Plaintiffs allege separately), nor of any claim for "lack of informed consent" against anyone other than a healthcare provider, *see* N.Y. Pub. Health Law § 2805-d.[3]

[3] Prevail agrees that New York law applies to the liability issues given Dr. Sugar's treatment in New York, but Maryland law might remain relevant on damages issues given Dr. Sugar's residence and the location where he suffered from and was treated for his alleged injuries.

Finally, Mrs. Sugar's claim for loss of consortium fails because such a claim is derivative of the tort claims, which, as noted, fail as a matter of law. *See Prohaska v. Sofamor, S.N.C.*, 138 F. Supp. 2d 422, 449 (W.D.N.Y. 2001).

Contract Claim

Plaintiffs' contract claim fails for two principal reasons. First, the sole basis for Plaintiffs' contract claim is a reference in the informed consent document to compensation for out-of-pocket expenses. Prevail was not a signatory to that document, and Plaintiffs do not allege that it was. *See* Complaint, ¶¶ 75-80 & Ex. A. Plaintiffs have therefore failed to allege the requisite meeting of the minds between Plaintiffs and Prevail. *See Duckett v. Williams*, 86 F. Supp. 3d 268, 272-73 (S.D.N.Y. 2015); *Suthers v. Amgen, Inc.*, 372 F. Supp. 2d 416, 425 (S.D.N.Y. 2005).

Second, and more fundamentally, Plaintiffs have not alleged facts that, if true, would establish any breach or other failure to comply with the consent provision addressing reimbursement for out-of-pocket expenses. Plaintiffs have not pleaded that they have provided Prevail with a description or accounting of expenses that were unreimbursed by insurance and "medically necessary . . . for the diagnosis and treatment" of a study-related injury, *see* Complaint, Ex. A, at 22, and that Prevail has declined such a demand for such reimbursement. As such, the Complaint does not allege a breach of any agreement.

* * *

Although Prevail is sympathetic to the challenges that Dr. Sugar has experienced, Plaintiffs have no basis to claim that Prevail engaged in any wrongdoing or is otherwise liable to Plaintiffs. Prevail therefore intends to move for dismissal of Plaintiffs' Complaint with prejudice.

Respectfully submitted,

/s/ Ryan A. Partelow

Counsel to Defendant Prevail Therapeutics Inc.